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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,336	12/13/2001	Bill Peck	10010408	6785

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EXAMINER	
LAIR, DONALD M	
ART UNIT	**PAPER NUMBER**
2858	

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,336	PECK, BILL	
	Examiner	Art Unit	
	Donald M. Lair	2858	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/3/03 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 3 – 14 and 19 – 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schleifer et al. (US-6,242,266) in view of Gibson et al. (US-6,119,506) and in view of Wohlstadter et al. (US-6,413,783)

4. In regards to Claims 1 and 19, Schleifer et al. disclose an apparatus comprising a body defining a chamber having first and second ports (Fig. 6, element 208), a first valve (Fig. 6, element 114; Column 10, lines 1 – 3) in communication with the first port, a second valve (Fig. 6, element 86; Column 10, lines 9 – 11) in communication with the second port, and a dry gas source (Fig. 6, element 88; Column 10, lines 6 – 7). The chamber is apart from an environment to be sampled for moisture by the capacitance sensor probe, wherein the environment to be sampled is the reagents used, and wherein the sampling conduit provides fluid communication

through the first port between the chamber and the environment (Column 11, lines 16 – 33). Schleifer et al. teach positioning the valves to allow dry gas to flow through the chamber in one state (Schleifer et al., Column 3, lines 8 – 13 and 59 – 66) and to also allow a sample to flow through the chamber in another (Schleifer et al., Column 7, lines 27 – 31; Column 8, lines 13 – 14). Schleifer et al. teach that reagents typically used in the preparation of biopolymer arrays are water sensitive and that the presence of moisture should be eliminated or minimized; however, the reference fails to teach using a capacitive sensor probe in the chamber. Schleifer et al. fail to explicitly state that the reagents used are a gaseous sample.

5. Gibson et al. teach using capacitive probes (Fig. 1, elements 102 and 104; Column 8, lines 47 – 51) in a closed chamber (Fig. 1, element 90; Column 8, lines 1 – 2) to detect the moisture content of the sample flowing across the probes (Column 9, lines 30 – 33).

6. Since Schleifer et al. teach that water can adversely affect the materials used in the production of biopolymer arrays and Gibson et al. teach a method of monitoring the moisture content of materials, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the chamber of the apparatus disclosed by Schleifer et al. to include a capacitance sensor probe as disclosed by Gibson et al. for the purpose of monitoring the moisture content of the current sample, wherein it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the device wherein the sample is a gaseous sample or solid sample or liquid sample.

7. Wohlstadter et al. teach that reagents may be used in any physical state, including gaseous. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention disclosed by Schleifer et al. by using gaseous

reagents as taught by Wohlstadter et al. for the purpose of producing the desired biopolymeric array. Gaseous samples had a recognized suitability as a replacement for solid or liquid samples at the time of invention and thus meet the requirements for a test of prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). MPEP 2144.07.*

8. In regards to Claim 3, Schleifer et al. teach placing a vacuum pump in fluid communication with the chamber to draw sample material into the chamber (Schleifer et al., Column 11, lines 16 – 27; Column 7, lines 27 – 31).

9. In regards to Claim 4, Schleifer et al. teach using a venturi device as the vacuum pump (Schleifer et al., Column 7, lines 27 – 33).

10. In regards to Claim 5, Schleifer et al. teach driving the venturi device with a dry gas source (Schleifer et al., Abstract, lines 15 – 17).

11. In regards to Claim 6, Schleifer et al. does not teach placing the ports of Claim 1 in an orthogonal arrangement, but does teach placing a third port (Schleifer et al., Column 11, lines 20 – 27) orthogonal to the first and second ports. Further, the third port disclosed by the reference is responsible for delivering reagents to the head similar to port (8) of the application. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus disclosed by Schleifer et al. by placing the ports in an orthogonal arrangement for the purpose of drawing fluid in an upstream direction into the chamber.

12. In regards to Claim 7, Schleifer et al. do not teach using three-way valves in conjunction with two-way valves in the configuration disclosed by the applicant. However, the applicant uses the three-way valves for the purpose of being able to use a single venturi pump for drawing both

dry gas and samples through the chamber. The Schleifer et al. reference discloses drawing both dry gas and samples through the chamber but teach using two dry gas and venturi sources (Schleifer et al., Column 11, lines 25 – 27), therefore the apparatus disclosed by the applicant is functionally identical to the valve/pump system disclosed by Schleifer et al.

13. In regards to Claim 8, Schleifer et al. teach flowing dry gas through the chamber to purge the area of undesired components, especially moisture (Schleifer et al., Column 3, lines 8 – 13 and 59 - 66). The modified invention applied to Claim 1 has capacitance sensors in the chamber, thus it is apparent that the dry gas used for purging the chamber of moisture will further purge the probes of moisture as well. Schleifer et al. do not explicitly teach stopping the flow of dry gas; however the disclosure makes it quite apparent that the gas is used to clear the chamber of any moisture prior to the process of drawing reagents in, therefore it is obvious that the flow of dry gas must be terminated before any sample is introduced. Schleifer et al. describe flowing sample reagents into the chamber (Schleifer et al., Column 11, lines 29 – 33), and thus also over the capacitance sensors of the modified invention, and from this it is clear that the reagents, which are drawn from a synthesis environment, are stored separately from the chamber and therefore the capacitance sensor. Schleifer et al. fail to explicitly teach using a gaseous sample, however it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention by using a gaseous sample for the purpose of creating biopolymeric arrays that require gaseous samples for production. *MPEP 2144.07.*

14. In regards to Claim 9, Schleifer et al. teach the importance of keeping the reagents out of contact with moisture and further purging the chamber of moisture with a flow of dry gas. Schleifer et al. fail to teach placing the sensor in a dry gas environment to maintain low water

content. Gibson et al. teach placing the capacitive sensors in an insulated chamber. It would have been obvious to one of ordinary skill in the art at the time the invention was made that is important to minimize all reagent contact with moisture, and the modified invention as applied to Claim 1 does in fact isolate the capacitance sensors in the presence of dry gas for the purpose minimizing the amount of moisture in the chamber.

15. In regards to Claims 10 and 20, Schleifer et al. teach using negative pressure created by a venturi pump to draw sample through a flow-cell (Schleifer et al., Column 2, lines 55 – 60; Column 3, lines 8 – 10; Column 4, lines 13 – 15).

16. In regards to Claim 11, the apparatus disclosed by Schleifer et al. is used to produce biopolymers (Schleifer et al., Column 1, lines 26 – 27; Column 2, lines 36 – 38).

17. In regards to Claim 12, Schleifer et al. disclose producing a nucleic acid (Schleifer et al., Column 6, lines 14 – 21).

18. In regards to Claims 13 and 14, Schleifer et al. disclose producing a biopolymer array (Schleifer et al., Column 1, lines 26 – 27; Column 2, lines 36 – 38; Column 8, lines 33 – 34).

19. In regards to Claim 21, Schleifer et al. teach driving the venturi device with a dry gas source (Abstract, lines 15 – 17).

20. Claims 15 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US-2003/0008413) in view of Schleifer et al. and in view of Gibson et al.

21. In regards to Claim 15, Kim et al. disclose a method of detecting the presence of an analyte in a sample comprising contacting a biopolymeric array having a complementary binding pair member (Paragraph 88) that specifically binds to said analyte, with a sample suspected of comprising said analyte under conditions sufficient for binding of said analyte to a biopolymeric

ligand on the array to occur, and detecting the presence of binding complexes on the surface of the array to detect the presence of the analyte in the sample (Claim 34). Kim et al. fail to disclose the steps of the method of production for the biopolymeric array.

22. The method of production disclosed by Schleifer et al. in view of Gibson et al., applied to Claim 1 and described extensively above, includes the limitations of "wherein said biopolymeric array is produced in a synthesis environment in which there is capacitance measurement for determining water content of a gaseous sample from the synthesis environment (Gibson et al., Fig. 1, elements 90, 102 and 104), said measurement comprising (i) flowing dry gas over a capacitance sensor apart from said synthesis environment so said sensor desorbs water (Schleifer et al., Column 3, lines 8-10; Column 4, lines 13-15), terminating said flowing of dry gas, and (ii) flowing said gaseous sample from said synthesis environment over said sensor to measure water content of said sample" as described above. Schleifer et al. do not explicitly teach stopping the flow of dry gas; however the disclosure makes it quite apparent that the gas is used to clear the chamber of any moisture prior to the process of drawing reagents in, therefore it is clear that the flow of dry gas must be terminated before any sample is introduced.

23. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of detecting disclosed by Kim et al. by using the method of production disclosed by Schleifer et al. in view of Gibson et al. for the purpose of having a produced biopolymeric array to detect.

24. In regards to Claim 16, Kim et al. disclose transmitting a result from the detecting step (Paragraph 91, lines 1 – 4).

25. In regards to Claim 17, Kim et al. disclose communicating the result to a remote location (Paragraph 91, lines 1 – 4).

26. In regards to Claim 18, Kim et al. disclose a method as applied to Claim 15 wherein data regarding a test sample is collected. It is inherent that there must be a way to receive data representing a result of the applied test in order to analyze the outcome otherwise the system would serve no function.

Response to Arguments

27. Applicant's arguments with respect to claims 15-18 have been considered but are moot in view of the new ground(s) of rejection.

28. Applicant's arguments filed 08-04-03 have been fully considered but they are not persuasive.

29. The sampling conduit is described as providing "fluid communication through said first port between said chamber and the environment." Schleifer et al. disclose this at Column 11, lines 16-33, wherein lines 112 and 97 may be interpreted to meet the limitations. Futher, the "delivery chambers" also meets the limiations. Gibson et al. show this at Fig. 1, elements 36, 38, 50 and 90.

30. In regards the arguments made referring to Claims 1 and 19, the Applicant asserts that the use of gaseous sample is patentable over the cited references. The Examiner disagrees. The cited art is clearly capable of passing gas through the chamber and does so. The reference further teaches passes sample through the chamber. it would have been obvious to one of ordinary skill in the art at the time the invention was made that samples/reagents come in all physical forms including gaseous. Gaseous samples had a recognized suitability for the purpose of producing

biopolymeric arrays at the time of invention and thus meet the requirements for a test of prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). MPEP 2144.07.*

31. In regards the arguments made against the rejection of Claim 19 referring to the "distinct system configurations of valve states" Schleifer et al. do not explicitly teach stopping the flow of dry gas; however the disclosure makes it quite apparent that the gas is used to clear the chamber of any moisture prior to the process of drawing reagents in, therefore it is clear that the flow of dry gas must be terminated before any sample is introduced.

32. In regards to the Applicant's assertions that the "reference allows for no sample flow as noted above" the venturi pump is used to draw both sample (Column 11, lines 25 – 27) and dry gas (Column 12, lines 61 – 65). The Applicant continues to state that "such activity is believed to be a physical impossibility (regardless of what one might try to read into the text of the patent" but he fails to state *why* he feels it is a physical impossibility. As such, there is nothing for the Examiner to respond to.

33. In regards to the Applicant's arguments referring to Claim 10, the Schleifer reference clearly teaches using a source of vacuum/venturi pump to draw sample through a flow cell (Column 11, lines 16 – 33).

34. Finally, the Applicant asserts that "Schleifer and Gibson are not properly combined at all." His basis for this assertion is that the "reservoir in Schleifer is not amenable to placement of a sensor therein. It includes a septum and is intended to be (completely) filled with fluid. If it were not, the utility of the apparatus would be compromised – if not destroyed.)." It is the examiner's position that presence of the sensor in the septum does not prevent the septum from

being completely filled, the only difference is that the septum would have a decreased max volume. If the max volume is critical, the problem could be easily fixed by using a larger septum capable of containing the sensor and the required amount of reagent/sample.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donald M. Lair whose telephone number is (703) 305-4450. The examiner can normally be reached on Monday - Friday, 8 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, N. Le can be reached on (703) 308-0750. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9318.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1436.

Donald M. Lair
Patent Examiner
Art Unit 2858
November 13, 2003

N. Le
Supervisory Patent Examiner
Technology Center 2800